UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,610	02/26/2004	Jingrong Jean Cui	034536-1148	2828

22428 7590 03/30/2006

FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
TUCKER, ZACHARY C	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/786,610	CUI ET AL.	
	Examiner	Art Unit	
	Zachary C. Tucker	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) *2,6,8,10,11,15,17,19-29,32,33,36,37 and 39-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7,9,12-14,16,18,30,31,34,35 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

A Requirement for Restriction for the instant application was set out in an Office letter mailed 30 January 2006. In the reply thereto, filed 28 February 2006, applicants have elected with traverse to prosecute the invention of Group I, chemical compounds of formulae **1**, **2**, **3**, **4**, **5** and **6**. It should be noted that in the Requirement for Restriction letter, the class/subclass provided for Group I should have also included class *546*, for compounds of formulae **1**, **2** , **4** and **6** - pyridine compounds (where "Y" is CR^{12}), in addition to class 544, for pyrazine compounds (where "Y" is N).

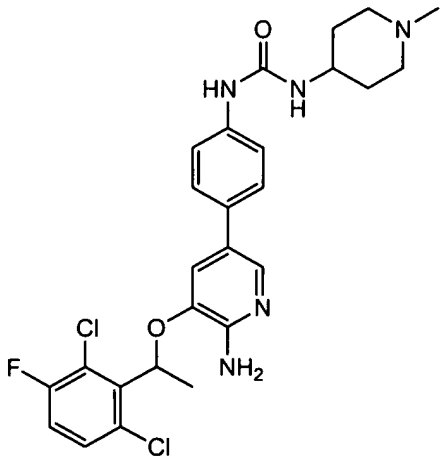
Applicants' traversal of the restriction requirement at hand is on the ground that there is no undue burden posed by searching all claims in the application at once. This is not found persuasive because, first, a showing of separate classification is evidence of a search burden. According to the MPEP §803, "...a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02. That *prima facie* showing may be rebutted by appropriate showings or evidence by the applicant." Applicant has made no rebuttal of the examiner's showing of separate classification and separate status in the art. Thus, a serious burden has been established. Second, in determining the patentability of the methods as are set forth in Groups II and III, the examiner will be required to make an evaluation of the state of the art with respect to the treatment of diseases and conditions embraced by those method claims, as well as the state of the art with respect to the clinical and therapeutic application of drugs having activities the same as or similar to the compounds according to the instant claims. This additional survey of the medical

literature is made to determine compliance of the claims with the first paragraph of 35 U.S.C. 112, and is not required when conducting a search for simple disclosures of compounds, which is all that is required for determination of patentability of the invention of Group I. So, the search required for Groups II and III is considerably more involved that is required for Group I.

The requirement is still deemed proper and is therefore made FINAL.

Thus, claims 44-48 are withdrawn from further consideration at this time pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions. Applicant timely traversed the restriction requirement in the reply filed on 28 February 2006. Claims of the nonelected Groups are eligible for rejoinder, as explained in the Requirement for Restriction letter.

Also in the Requirement for Restriction letter, a further requirement was set out for applicants to elect a single disclosed species, for examination purposes, from which a search of the prior art would begin. In response, applicants' counsel indicated the compound of Example I-377, named 1-(4-{6-amino-5-[1-(2,6-dichloro-3-fluoro-phenyl)-ethoxy]-pyridin-3-yl}-phenyl)-3-(1-methyl-piperidin-4-yl)-urea, whose molecular structure is shown here:



Claims which read on this species are 1, 3-5, 7, 9, 12-14, 16, 18, 30, 31, 34, 35 and 38, as pointed out by applicants' counsel in the reply. Claims 44-48 do not encompass the species elected for examination, contrary to the remarks provided by applicants' counsel, because they are drawn to methods, which are not part of the subject matter of the elected Group.

A search of the prior art, based on the structure of the elected species, was begun. When R^1 is a cyclic group (any of the cyclic groups provided for in R^1); R^2 is hydrogen (H); Y is CR^{12} with R^{12} being hydrogen (H); "n" in A^1 being 0-4; and A^2 being any identity provided for in the claims under examination (those claims that are *not* withdrawn, that is), there is no prior art anticipating or rendering obvious any such compounds. The search was expanded to include compounds according to the instant claims wherein R^1 is not limited to only cyclic groups, with all of the other variables as described in the previous sentence. Prior art rendering several of the instant claims unpatentable was found, whereupon the search was stopped. None of claims 1, 3-5, 7, 9, 12, 13, 14, 16, 18, 30, 31, 34, 35 and 38, therefore, have been completely searched.

Claims 2, 6, 8, 10, 11, 15, 17, 19-29, 32, 33, 36, 37 and 39-43 are withdrawn from consideration as not readable on the elected species, addition to those claims (claims 44-48) withdrawn from consideration as being drawn to nonelected inventions.

Obviousness-Type Double Patenting

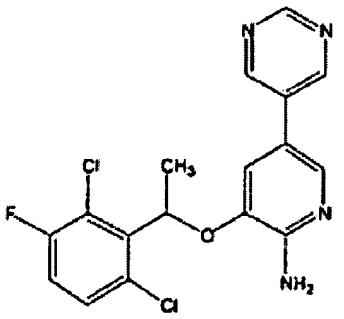
The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

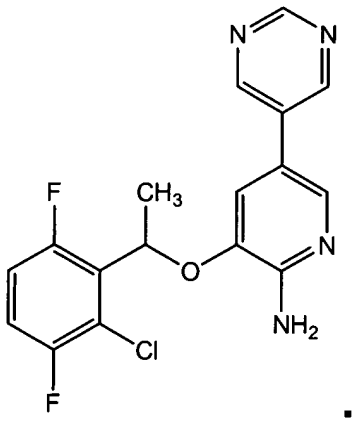
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-5, 7, 9, 12-14, 16, 18, 30, 31, 34, 35 and 38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 11/213,038. Although the conflicting claims are not identical, they are not patentably distinct from each other because compounds specified in claim 5, and therefore also the compounds embraced by claims 1-4 of the copending application anticipate the instant claims; if the claims of the copending application were prior art, the instant claims would be anticipated by said claims. To wit, compounds according to claim 5 of application serial number 11/213,038 anticipate instant claims 1, 3-5, 7, 9, 12-14, 16, 18, 30, 31, 34 and 35 wherein R^1 is 6-membered heteroaryl (pyrimidinyl); R^2 is hydrogen (H); "n" of A^1 is equal to 1, R^9 in A^1 is H, R^{10} of A^1 is alkyl (methyl) and A^2 in A^1 is 6-membered aryl (phenyl), substituted with 3 R^3 groups which are halogen – A^2 forms a 1-(2,6-dichloro-3-fluoro-phenyl)eth-1-yl group. The compound according to claim 5 of the copending application having the structure shown at the top of the next page:



is one such compound.

Instant claim 38 includes among a vast number of others, includes one species named 3-[1-(2-chloro-3,6-difluoro-phenyl)-ethoxy]-5-pyrimidin-5-yl-pyridin-2-ylamine, appearing at page 303 of the claims, in lines 14-15, and having this structure:



It has been decided by the BPAI that a chlorine substitution renders a corresponding fluorine substitution obvious (*Ex Parte* Wiseman 98 USPQ 277). Therefore then, the above-indicated compound from claim 38 of the instant application is properly regarded as an obvious variant of the above-indicated compound from claim 5 of the copending application. The examiner would submit that one of ordinary skill in the art, therefore, would consider the indicated species from instant claim 38 to be no more than an obvious variant of the indicated species from claim 5 of the copending application. Replacement of the 2-chlorine atom in the species from the copending

application with a fluorine atom, as is present in the species from claim 38 of the instant application, is no more than an obvious modification.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-5, 7, 9, 12-14, 16, 18, 30, 31 and 38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds according to formulae **1**, **2**, **4** and species named in claim 38, their pharmaceutically acceptable salts and hydrates, does not reasonably provide enablement for solvates of said compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the full scope of the invention specified in these claims. "Solvates" of the compounds specified in the claims necessarily embraces every possible stoichiometry of molecules of compound to solvent molecule for every one of the compounds embraced by the instant claims, for every solvent known. This amounts to a scope so broad so as to be inconceivable in the sheer number of individual solvates. Every compound according to the indicated claims, solvated with every *solvent* is the extent of the exclusive right sought by applicants by virtue of this claim language.

In making the determination of whether certain embodiments of a claimed invention are enabled by the disclosure, the Office relies on the following factors:

(A) The breadth of the claims;

(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.
In re Wands, 858 F.2d 731,737 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

(A) Insofar as the solvate embodiment of claims 1, 3-5, 7, 9, 12-14, 16, 18, 30, 31 and 38 is concerned, those claims read on solvates of compounds according to formulae **1**, **2**, **4** and species named in claim 38. The scope of the solvates recited in the claims includes all solvates of said compounds, with *all* solvents. The definition of a solvate, taken from the Vippagunta et al reference, cited in section (C), (D), (E) below, is a "crystalline solid adduct[s] containing solvent molecules within the crystal structure, in either stoichiometric or nonstoichiometric proportions, giving rise to unique differences in the physical and pharmaceutical properties of the drug."

(B) The nature of the invention is that of all solvates of a very large family of chemical compounds, with any solvent. Solvates represent a special physical form of chemical compounds.

(C), (D), (E) Solvates, at the time the invention was made, were known and characterized, but their formation and production was not understood to such an extent that the directed preparation of specific solvates was routine or simple. The following references address the state of the art with respect to crystalline forms of organic compounds, formation of solvates of organic compounds, and the predictability thereof.

Vippagunta et al, "Crystalline Solids" Advanced Drug Delivery Reviews, vol. 48, pages 3-26 (2001).

and

Gavezzotti, "Are Crystal Structures Predictable?" Accounts of Chemical Research, vol. 27, pages 309-314 (1994).

First, it is evident from both of the references that formation of specific crystalline forms, and more particularly, solvates, is highly unpredictable. See Gavezzotti, page 312, point #8, and Vippagunta et al, page 11, "Prediction of Polymorphs" and page 18 "Prediction of the formation of hydrates and solvates."

Because the formation of solvates is unpredictable, even the relatively high level of skill possessed by one of ordinary skill in the art is not enough to render preparation of solvates routine. Each solvate of each compound must be experimentally prepared (since the conditions necessary for the formation cannot be predicted), wherein all of the factors relevant to each individual compound's ability to crystallize and form solvates are studied. These factors are identified in points #1-7 of the Gavezzotti reference. The preparation of each single claimed solvate represents a significant undertaking in the areas of preparative organic chemistry, physical chemistry, and crystallographic measurements.

It is unknown that the full scope of solvates of compounds of formula (I) is even possible (see Gavezzotti, page 309, point #1).

(F) There is no teaching in the specification germane to the preparation of solvates. The specification only mentions solvates of the compounds disclosed therein; each description of a particular embodiment of the invention is concluded with "or a pharmaceutically acceptable salt, solvate or solvate thereof;" that is the extent of the description of solvates found in the disclosure.

(G) No working examples of the preparation of any solvate is in the disclosure.

(H) Each chemical compound according to the instant claims of which there are millions, as a solvate with every known solvent, of which there are also millions, represents the efforts of many over a period of years. Those efforts would likely be inconclusive, as billions and billions of distinct solvates are embodied in the claims. . For one of ordinary skill in the art to conduct the type of research outlined in Gavezzotti and in Vippagunta et al for preparation of every one of the claimed solvates would be undue. Applicants' right to exclude others from making solvates of compounds according to formulae **1**, **2**, **4** and all of the species named in claim 38, is unwarranted in light of the complete lack of any direction as to how one of ordinary skill would do so.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-5, 7, 9, 12-14, 16, 18, 30, 31, 34, 35 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each one of claims 1, 4, 5, 12, 13, 14, 30 and 31 recite one of both of the terms "heteroaryl" and "heteroalicyclic." Any other claim indicated as being rejected under 35 U.S.C. 112, second paragraph, in this section, is included in this rejection because it depends either directly or indirectly from some claim reciting one or both of "heteroaryl" and "heteroalicyclic."

In the instant specification, no definition is set forth for the term "heteroaryl" and "heteroalicyclic." Only some examples of what applicants intend for the terms to encompass are provided, by way of the preferred embodiments of the compounds

according to the invention. Therefore, to understand the full scope of what is embraced by these terms, one of ordinary skill would necessarily have to consult the literature as to their meaning.

More than one definition, however, of the general term "heterocyclic" or "heterocycle," or any term derived therefrom is accepted by those of ordinary skill in the art of organic chemistry.

Some consider cyclic organic compounds wherein at least one carbon atom is replaced by sulfur, oxygen or nitrogen to be heterocyclic compounds, while others of ordinary skill include selenium, tellurium, boron or tin containing rings to be within the scope of the term "heterocyclic" as it is commonly used, and some definitions of "heterocyclic" do not require carbon to present at all.

The examiner directs applicants' attention to the following three references:

On page 200 of the McGraw-Hill Dictionary of Chemical Terms, the definition of "heterocyclic compound" is a compound in which the ring structure is a combination of more than one kind of atom.

On page 490 of the Concise Encyclopedia Chemistry, the definition of "heterocycles" is cyclic hydrocarbon compounds in which the ring consists of carbon and at least one other element, usually, N, O or S. The definition goes on to explain that the possibilities for synthesis are nearly unlimited, and that compounds wherein the heteroatoms are of elements like phosphorous, arsenic, selenium, and tellurium are being incorporated with increasing frequency.

On page 594 of Hawley's Condensed Chemical Dictionary, "heterocyclic" is defined as a closed-ring structure, usually, either 5 or 6 members, in which one or more of the atoms in the ring is an element other than carbon, *e.g.* sulfur, nitrogen, *etc.*

These three definitions should make it abundantly clear that there is no one specific and exact definition of the word "heteroaryl" or "heteroalicyclic," thus when this term is present as a claim limitation, the metes and bounds of protection are not pointed out and distinctly claimed. Though the three above-cited definitions of the term have some shared aspects, chemists of ordinary skill would not necessarily agree on their full scope and meaning.

Applicants may argue that since some examples of what the broad terms "heteroaryl" and "heteroalicyclic" embrace have been provided in the specification, then the terms when recited as claim limitations are definite.

The examiner would respond by pointing out the fact that while it is proper to use the specification to interpret what the applicant meant by a word or phrase recited in the claim, it is **not** proper to read limitations appearing in the specification into the claim when these limitations are not recited in the claim. See *In re Paulsen;* 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994); *Intervet America Inc. v. Kee-Vet Lab. Inc.,* 887 F.2d 1050, 1053, 12 USPQ2d 1474, 1476 (Fed. Cir. 1989).

It is suggested that applicants incorporate a more specific definition for "heteroaryl" and "heteroalicyclic," such as is provided in instant claim 9, into claims reciting those terms, to overcome this rejection. There does not appear to be support in the instant specification for an amendment to the claims introducing a general definition of the terms (which would be acceptable, provided there were support) along the lines of (for heteroaryl): "a 5- or 6-membered aromatic ring containing 1 to 3 heteroatoms selected from the group consisting of oxygen, nitrogen and sulfur."

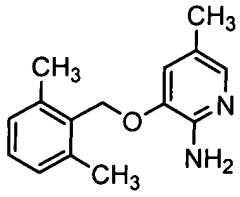
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 12, 13, 30 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/37080 (Amin et al).

The Amin et al publication discloses imidazo[1,2-a]pyridine compounds for inhibition of gastric acid secretion. An intermediate employed in the synthesis of the gastric acid secretion-inhibiting compounds is 2-amino-3-(2,6-dimethyl)benzyloxy-5-methyl-pyridine (page 54, Example 2.21):

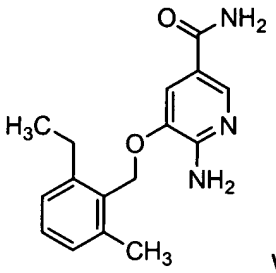


which is a compound embraced by instant claims 1, 3, 4, 12, 13, 30 and 31 wherein R^1 is methyl; R^2 is H; A^1 is 2,6-dimethylbenzyl (n=1, 2 R^3 substitutions which are methyl, on a 6-membered aryl group; a phenyl ring); Y is CR^{12}, where R^{12} is H..

Claims 1, 3, 4, 12, 13, 30 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,313,137 (Amin et al '137).

Amin et al '137 discloses imidazo[1,2-a]pyridine compounds for inhibition of gastric acid secretion. An intermediate employed in the synthesis of the gastric acid

secretion-inhibiting compounds is 6-amino-5-(2-ethyl-6-methylbenzyloxy)-nicotinamide (Example 2.27, column 31, lines 19-32):



which is a compound embraced by instant claims 1, 3, 4, 12, 13, 30 and 31 wherein R^1 is $-C(O)NR^4R^5$, R^4 and R^5 being H; R^2 is H; Y is CR^{12}, R^{12} being H; A^1 is 2-ethyl-6-methylbenzyl (n=1, one R^3 is ethyl and another R^3 is methyl, on a 6-membered aryl group, a phenyl ring)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,313,137 (Amin et al '137).

Amin et al '137 is applied against claims 7 and 16 as set forth above in the rejection of claims 1, 3, 4, 12, 13, 30 and 31 under 35 U.S.C. 102(b).

At the time the invention was made, a compound according to claim 7 or 16 would have been obvious to a student of Amin et al '137 of ordinary skill in the art.

The deficiency of the Amin et al patent with respect to instant claims 7 and 16 is that no compound according to claims 7 and 16 is disclosed therein. As will be shown, however, such a compound is in fact expressly suggested by the reference.

In the case of Amin et al '137, the imidazo[1,2-a]pyridine compounds according to the invention disclosed therein are prepared with specific intermediates necessary for their preparation. The benzyloxy group of the compound 6-amino-5-(2-ethyl-6-methylbenzyloxy)-nicotinamide (Example 2.27, column 31, lines 19-32), which forms the basis for the rejection under 35 U.S.C. 102(b) of the instant claims over the Amin et al '137 patent is the source of the phenyl ring in those imidazo[1,2-a]pyridine compounds of the general Formula I shown in column 1, lines 50-65, of Amin et al '137. The groups R^3, R^4 and R^5 in Amin et al's formula (I) are the substitutions on the benzyl group in the intermediates which are employed to make the compounds. Preparation of these intermediate compounds is taught in columns 24 (lines 63-67) to column 31, line 31.

A chemist of ordinary skill in the art understands the teachings in a patent to be particularly applicable to the preferred embodiments, that is, to the compounds which were actually made by the inventors in the reduction to practice of the invention disclosed in such a publication. Bearing this in mind, one of ordinary skill in the art of drug design and preparative medicinal/organic chemistry, motivated by a desire to make the gastric acid secretion-inhibiting compounds taught by Amine et al, would have found it obvious to make an imidazo[1,2-a]pyridine of the general formula (I) as taught in that patent, with a halogen substitution on the aforementioned benzyloxy group. This substitution is expressly suggested in the patent at column 2, lines 8-21. Halogen is suggested as a substituent at each one of R^3, R^4 and R^5. One of the exemplified compounds according to Amin et al in fact does bear a halogen substitution on the portion of the molecule corresponding to the benzyloxy group found in the necessary intermediates – Example 1.18, in column 22. It is noted that in this particular

imidazo[1,2-a]pyridine compound, the group corresponding to "X" in general formula (I) according to Amin et al is a nitrogen atom, as opposed to an oxygen atom, but the fact remains that halogen is expressly suggested as a substituent on the benzyloxy group of the formula (I) compound, and one of the exemplified embodiments of such compounds bears a halogeno-substituent on this portion of the molecule. So, a formula (I) compound, such as the one described in Example 1.22, wherein "X" is oxygen, and wherein on the benzyloxy group, a halogen atom is situated, is clearly in the teaching of Amin et al. An intermediate compound, such as the one noted in Example 2.27 of the Amin et al patent, and relied upon in the rejection of instant claims 1, 3, 4, 12, 13, 30 and 31 under 35 U.S.C. 102(b) over Amin et al, set forth above, wherein a halogen atom substitutes the phenyl ring, would be necessary in producing a formula (I) compound wherein the benzyloxy group comprises a halogen atom.

Applicants may opine that because the motivation provided in this rejection under 35 U.S.C. 103 (desire to make specific intermediate compounds for imidazo[1,2-a]pyridine compounds) differs from the motivation of applicants in producing the compounds according to the instant invention (desire to make kinase inhibiting compounds), the rationale provided is not valid and the rejection is not tenable. The examiner would point out that the motivation provided in a rejection under this statute may differ from applicants' motivation (MPEP 2144 discusses pertinent case law under the heading "RATIONALE DIFFERENT FROM APPLICANT'S IS PERMISSIBLE").

Declaration

In the Requirement for Restriction letter, there was made an objection to the declaration in the instant application, as it had appeared that inventor Iriny Botrous' signature had been lined through. As it happens, which is apparent from the appendix

that applicants' counsel has submitted with the reply to the Requirement for Restriction, Ms. Botrous normally signs her name this way. The objection is therefore withdrawn.

Allowable Subject Matter

Claims 34 and 35, should the rejection under 35 U.S.C. 112, second paragraph, and the Obviousness-Type Double Patenting rejection be overcome, would be allowable. No compound according to formula **6** or any pharmaceutically acceptable salt thereof, is disclosed or suggested in the prior art. The closest prior art with respect to formula **6** compounds is the two references relied upon in rejections under 35 U.S.C. 102 and 103 in this Office action. As mentioned in the section headed "Election/Restrictions," the compounds of formulae **1**, **2** and **4**, where R^1 is a cyclic group (any of the cyclic groups provided for in R^1); R^2 is hydrogen (H); Y is CR^{12} with R^{12} being hydrogen (H); "n" in A^1 being 0-4; and A^2 being any identity provided for in the claims under examination (those claims that are *not* withdrawn, that is) are not disclosed or suggested in the prior art either. An amendment to the claims limiting formula **1**, **2** and **4** compounds to those compounds wherein Y is CR^{12}, R^{12} being H; R^1 is some cyclic group provided for in the definition thereof (provided that the indefiniteness rejection of "heteroaryl" and "heteroalicyclic" is overcome); R^2 is H; A^1 is as provided for in the claims in their present form (provided the indefiniteness rejection of "heteroaryl" and "heteroalicyclic" is overcome), would be allowable, should the double patenting rejection be overcome. The point of novelty of such compounds, generally, is the cyclic substituent at R^1.

Comment

The proviso recited in the latter part of claim 1, is no longer pertinent to compounds according to the elected species, namely pyridine compounds, because "Y"

is not N in these compounds. Corollary "(i)" of the proviso, it is noted, appears to be slightly redundant, in that the condition states that when Y is N and R^1 is substituted or unsubstituted aryl or substituted or unsubstituted heteroaryl, then A^1 is $-(CR^9R^{10})_n-A_2$. A^1 is $-(CR^9R^{10})_n-A_2$ in all cases anyway – the proviso should be rewritten to simply state that under condition "(i)," n is not equal to zero. This issue is moot, however, because the entire proviso does not apply to the pyridine compounds elected for prosecution.

Conclusion

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Tuesday-Thursday from 8:00am to 4:30pm or Monday from 6:00am to 1:30pm. If Attempts to reach the examiner are unsuccessful, contact the examiner's supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

zt